DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-88

September 19, 2001

Larry D. Rutt, Operations Manager
Camtronics LTD., Medical Systems
809-C S. Orlando Avenue
Winter Park, Florida 32789

Dear Mr. Rutt:

During an inspection of your establishment located in Winter Park, Florida on July 17-19, 2001, FDA Investigator Ronald T. Weber determined that your establishment is a manufacturer and distributor of the CAAT physiological monitoring station, which is a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Federal Food, Drug, and Cosmetic Act (the Act), the product that your firm manufactures is considered to be a medical device that is used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The above-stated inspection revealed that the device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm failed to establish and maintain adequate procedures for implementing corrective and preventive action, as required by 21 CFR 820.100. For example, written procedures fail to identify actions needed to correct and prevent recurrences of nonconforming product and other quality problems; to verify or validate corrective and preventive actions to ensure that action is effective and does not adversely affect the finished device; to record

and implement changes in methods and procedures needed to correct and prevent quality problems; disseminate information related to quality problems to those directly responsible for assuring the quality of the product or for preventing quality problems; to submit information related to quality problems to management for review: and analyze all sources of quality data to identify existing and potential causes of nonconforming product and other quality problems (FDA 483, Item #1).

2. Your firm failed to adequately analyze complaint quality data using appropriate statistical methodology to detect recurring quality problems, as required by 21 CFR 820.100(a)(1). For example, complaints are not analyzed to determine other failure modes that may be the source of the identified problem (FDA 483, Item #7).

3. Your firm failed to establish and maintain adequate installation and inspection instructions, and where appropriate test procedures, and to document the inspection and any test results demonstrating the proper installation of the device, as required by 21 CFR 820.170. For example, only about 30% of all Trip Reports are being forwarded to the manufacturing facility responsible for installation and any corrective action that may be required due to unexpected problems or non-conformance of the device (FDA 483, Item #2).

4. Your firm failed to establish adequate procedures for identifying training needs and to ensure that all personnel are trained to perform their assigned duties, including documentation of all training, as required by 21 CFR 820.25(b). For example, the individual responsible for most of the manufacturing has not received any in-house or formal QS/GMP training, and training received by employees is not documented (FDA 483, Item #s 5 & 6).

MEDICAL DEVICE REPORTING

Your devices are misbranded within the meaning of section 502(t)(2) in that your firm failed to develop, maintain and implement adequate written MDR procedures, and failed to furnish material or information required by or under section 519 respecting the devices. These violations include, but are not limited to the following:

5. Your firm failed to develop, maintain and implement adequate written MDR procedures as required by 21 CFR 803.17. For example, there are no provisions to report failures that do not concern death or serious injury (FDA 483, Item #3).

6. Your firm failed to submit a report filed with you, identified as MedWatch Report #26041-1999-008, which reported the lock-up of the hospital's recording system. The incident reportedly occurred during an emergency cardiac stent placement and delayed the reprofusion time by more than ten minutes (FDA 483, Item #4).

The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Emma Singleton
Director, Florida District